K010456

JUN 2 0 2001

SECTION E: 510(k) Summary

510(k) SUMMARY
This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
   February 9, 2001

2. **Applicant Information:**
   Polymer Technology Systems, Inc.
   7736 Zionsville Road
   Indianapolis, IN 46268

   Contact Person: Margo Enright
   Phone Number: 317-870-5610
   FAX Number: 317-870-5608

3. **Trade Name:**
   BioScanner Creatinine Test Strips

4. **Common Name:**
   Creatinine test system
   Panel: Clinical Chemistry 75
   Product Code: JFY

5. **Establishment Registration Number:**
   1836135

6. **Facility Address:**

   7736 Zionsville Road
   Indianapolis, IN 46268

7. **Device Classification:** Class II (Regulation: 21 CFR 862.1225)

   Intended Use:
   The BioScanner Creatinine Test is intended to measure creatinine in whole blood.

8. **Reason for 510(k):**
   New product

9. **Predicate Device Information**
   The following is the predicate device for determination of substantial equivalence:
   Name: Roche Creatinine Plus
   Device Company: Roche
   510(k) Number: K003261

Similarities and Differences Between BioScanner and Predicate Device

Similarities

- Both systems determine total creatinine concentrations in blood.
- Both use a photometer to convert the intensity of color produced in a colorimetric chemical reaction into a creatinine result.
- In both systems, the color of the end product is measured and converted into creatinine concentration and reported in mg/dL

Differences

1. The color development media.

- The BioScanner Creatinine Test Strips develop color on a dry membrane.
- The predicate device is a wet chemistry. The color is developed in a solution..

2. The method of red blood cell separation:

- The BioScanner Creatinine Test Strip separates the red blood cells, allowing the developed color to be read on the reaction area of the membrane.
- The predicate method does not separate out the red blood cells. The whole blood must be centrifuged to separate the red blood cells.

3. The calibration method.

- The BioScanner Creatinine Test Strips contain a lot specific electronically erasable programmable read-only memory (EEPROM) chip in the same package with the strips. The EEPROM chip has the curve information programmed into it based on a multipoint curve that is established for the lot. The user inserts this chip into the meter with each new lot of test strips. This chip is programmed with information that ensures that the correct lot of strips is used with the chip. There is a built-in failsafe:If the memory chip and strip lot number do not match, the user will get an error message that keeps the user from running the test until the strip and memory chip are matched.
- The predicate method requires the running of a calibrator with reagent to set a factor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 0 2001

Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: 510(k) Number: K010456
Trade/Device Name: BioScanner Creatinine Test Strips
Regulatory Class: Class II
Product Code: JFY
Dated: May 31, 2001
Received: June 1, 2001

Dear Ms. Enright:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

U.S. Food and Drug Administration - Center for Devices and Radiological Health

510(k) Number (if known): **K010456**

Device Name: **BioScanner Creatinine Test Strips**

Indications for Use:

The BioScanner Creatinine Test Strips are intended to measure creatinine in whole blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010456

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use X
(Per 21CFR 801.109)